3. A record shall be made by the pharmacy technician of the entry to include the date and time of entry; the name and signature of the pharmacy technician; the name, title, and signature of the person accompanying the pharmacy technician; the pharmacist's name granting permission to enter and telephone number where the pharmacist was reached; the name of the patient initially requesting needed medication and the nature of the emergency; a listing of all prescriptions retrieved during that entry; and the time of exit and re-securing of the prescription department.

4. The pharmacy technician shall reseal the key and alarm access code after the pharmacy is re-secured, and the PIC shall have the alarm access code changed within 48 hours of such an entry and shall document that this has been accomplished on the record of entry.

5. All records related to entry by a pharmacy technician shall be maintained for a period of one year on premises.

**18VAC110-20-200. Storage of drugs, devices, and controlled paraphernalia; expired drugs.**

A. Prescriptions awaiting delivery. Prescriptions prepared for delivery to the patient may be placed in a ~~secure place~~ secured area outside of the prescription department, not accessible to the public, ~~and~~ where access to the prescriptions is restricted to individuals designated by the pharmacist ~~to designated clerical assistants~~. With the permission of the pharmacist, the prepared prescriptions may be transferred to the patient at a time when the pharmacist is not on duty. If a prescription is delivered at a time when the pharmacist is not on duty, written procedures shall be established and followed by the pharmacy which detail security of the dispensed prescriptions and a method of compliance with counseling requirements of §54.1-3319 of the Code of Virginia. Additionally, a log shall be made and maintained of all prescriptions delivered to a patient when a pharmacist is not present to include the patient's name, prescription number(s), date of delivery, and the signature of the person receiving the prescription. Such log shall be maintained for a period of one year.

B. Dispersion of Schedule II drugs. Schedule II drugs shall either be dispersed with other schedules of drugs or shall be maintained within a securely locked cabinet, drawer, or safe. The cabinet, drawer, or safe may remain unlocked during hours that the prescription department is open and a pharmacist is on duty.

C. Safeguards for controlled paraphernalia and Schedule VI medical devices. Controlled paraphernalia and Schedule VI medical devices shall not be placed in an area completely removed from the prescription department whereby patrons will have free access to such items or where the pharmacist cannot exercise reasonable supervision and control.

D. Expired, or otherwise adulterated or misbranded drugs; security. Any drug which has exceeded the expiration date, or is otherwise adulterated or misbranded, shall not be dispensed or sold; it shall be separated from the stock used for dispensing. Expired prescription drugs shall be maintained in a designated area within the prescription department until proper disposal.

**18VAC110-20-210. Disposal of drugs by pharmacies.**

If a PIC wishes to dispose of unwanted drugs, he shall use one of the following procedures:

1. Transfer the drugs to another person or entity authorized to possess or provide for proper disposal of such drugs; or

2. Destroy the drugs by burning in an incinerator, or other board-approved method, in compliance with all applicable local, state, and federal laws and regulations. If Schedule II through V drugs are to be destroyed, the following procedures shall apply:

a. At least 14 days prior to the destruction date, the PIC shall provide a written notice to the board office; the notice shall state the following:

(1) Date, time, manner, and place of destruction.

(2) The names of the pharmacists who will witness the destruction process.

b. If the destruction date is to be changed or the destruction does not occur, a new notice shall be provided to the board office as set forth above in subdivision 2 of this section.

c. The actual destruction shall be witnessed by the PIC and another pharmacist not employed by the pharmacy.



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d. The DEA drug destruction form shall be fully completed and used as the record of all drugs to be destroyed. A copy of the destruction form shall be retained at the pharmacy with other inventory records.

**18VAC110-20-240. Manner of maintaining records, prescriptions, inventory records.**

A. Each pharmacy shall maintain the inventories and records of drugs as follows:

1. Inventories and records of all drugs listed in Schedules I and II shall be maintained separately from all other records of the pharmacy. Each pharmacy shall maintain a perpetual inventory of all Schedule II drugs received and dispensed, with reconciliation at least every thirty days. Electronic monitoring at the pharmacy or by another entity that provides alerts for discrepancies between drugs received and drugs dispensed is acceptable provided such alerts are reviewed at least monthly.

2. Inventories and records of drugs listed in Schedules III, IV, and V may be maintained separately or with records of Schedule VI drugs but shall not be maintained with other records of the pharmacy.

3. All executed order forms, prescriptions, and inventories of Schedule II through V drugs shall be maintained at the same ~~location~~ address as the stock of drugs to which the records pertain. If authorized by DEA, other records pertaining to Schedule II through V drugs, such as invoices, may be maintained in an off-site database or in secured storage. All records in off-site storage shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

4. ~~In the event that an inventory is taken as the result of a theft of drugs pursuant to §54.1-3404 of the Drug Control Act, the inventory shall be used as the opening inventory within the current biennial period. Such an inventory does not preclude the taking of the required inventory on the required biennial inventory date.~~

~~5.~~ All inventories required by §54.1-3404 of the Code of Virginia shall be signed and dated by the person taking the inventory and shall indicate whether the inventory was taken prior to the opening of business or after close of business. A 24-hour pharmacy with no opening or closing of business shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.

5. Invoices or other records showing receipts of Schedule VI drugs shall be maintained, but may be stored in an electronic database or record; as an electronic image which provides an exact, clearly legible, image of the document; or in secured storage, either on or offsite. All records in offsite storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

6. All records required by this section shall be filed chronologically and maintained for a period of not less than two years from the date of transaction.

B. Prescriptions.

1. A hard copy prescription shall be placed on file for every initial prescription dispensed and be maintained for two years from the date of last refill. All prescriptions shall be filed chronologically by date of initial dispensing.

2. Schedule II drugs. Prescriptions for Schedule II drugs shall be maintained in a separate prescription file.

3. Schedule III through V drugs. Prescriptions for Schedule III through V drugs shall be maintained either in a separate prescription file for drugs listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescriptions of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than one inch high and filed in the prescription file for drugs listed in the usual consecutively numbered prescription file for Schedule VI drugs. However, if a pharmacy employs an automated data processing system or other electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

C. Chart orders.

1. A chart order written for a patient in a hospital or long-term care facility, a patient receiving home infusion services, or a hospice patient pursuant to §54.1-3408.01 A of the Code of Virginia shall be exempt from having to contain all required information of a written prescription provided:

a. This information is contained in other readily retrievable records of the pharmacy; and

b. The pharmacy maintains a current policy and procedure manual that sets out where this information is maintained and how to retrieve it and the minimum requirements for chart orders consistent with state and federal law and accepted standard of care.

2. A chart order may serve as the hard copy prescription for those patients listed in subdivision 1 of this subsection.

3. Requirements for filing of chart orders.

a. Chart orders shall be filed chronologically by date of initial dispensing with the following exception: If dispensing data can be produced showing a complete audit trail for any requested drug for a specified time period and each chart order is readily retrievable upon request, chart orders may be filed using another method. Such alternate method shall be clearly documented in a current policy and procedure manual.

b. If a single chart order contains both an order for a Schedule II drug and one or more orders for a drug in another schedule, where the Schedule II drug is not floor stocked, but is dispensed from the pharmacy pursuant to this order for the specific patient, the original order must be filed with records of dispensing of Schedule II drugs and a copy of the order placed in the file for other schedules.

**18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians.**

A. In addition to the acts restricted to a pharmacist in §54.1-3320 A of the Code of Virginia, a pharmacist shall provide personal supervision of compounding of extemporaneous preparations by pharmacy technicians.

B. ~~A pharmacist directly monitoring the activities of a person enrolled in an approved pharmacy technician training program who is performing the tasks restricted to a pharmacy technician prior to registration in accordance with §54.1-3321 D of the Code of Virginia shall not monitor more than two such trainees at the same time, and at no time shall a pharmacist supervise more than four persons performing technician functions to include technicians and trainees.~~ A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time.

C. After the prescription has been prepared and prior to the delivery of the order, the pharmacist shall inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of dispensing as a certification of the accuracy of, and the responsibility for, the entire transaction. Such record showing verification of accuracy shall be maintained on a pharmacy record for the required time period of two years, unless otherwise specified in regulation.

D. If a pharmacist declines to fill a prescription for any reason other than the unavailability of the drug prescribed, he shall record on the back of the prescription the word "declined"; the name, address, and telephone number of the pharmacy; the date filling of the prescription was declined; and the signature of the pharmacist.

E. If a pharmacist determines from a prescriber or other means that a prescription presented for dispensing is a forgery, the pharmacist shall not return the forged prescription to the person presenting it. The forged prescription may be given to a law enforcement official investigating the forgery; or it shall be retained for a minimum of 30 days before destroying it, in the event it is needed for an investigative or other legitimate purpose.

**18VAC110-20-275. Delivery of dispensed prescriptions.**

A. Pursuant to §54.1-3420.2 B of the Code of Virginia, in addition to direct hand delivery to a patient or patient's agent or delivery to a patient's residence, a pharmacy may deliver prescriptions to another pharmacy, to a practitioner of the healing arts licensed to practice pharmacy or to sell



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controlled substances, or to an authorized person or entity holding a controlled substances registration issued for this purpose in compliance with this section and any other applicable state or federal law.

B. Delivery to another pharmacy.

1. One pharmacy may fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup or direct delivery to the patient provided the two pharmacies have the same owner, or have a written contract or agreement specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with all applicable federal and state law.

2. Each pharmacy using such a drug delivery system shall maintain and comply with all procedures in a current policy and procedure manual that includes the following information:

a. A description of how each pharmacy will comply with all applicable federal and state law;

b. The procedure for maintaining required, retrievable dispensing records to include which pharmacy maintains the hard-copy prescription, which pharmacy maintains the active prescription record for refilling purposes, how each pharmacy will access prescription information necessary to carry out its assigned responsibilities, method of recordkeeping for identifying the pharmacist or pharmacists responsible for dispensing the prescription and counseling the patient, and how and where this information can be accessed upon request by the board;

c. The procedure for tracking the prescription during each stage of the filling, dispensing, and delivery process;

d. The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription;

e. The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information;

f. The policy and procedure for ensuring accuracy and accountability in the delivery process;

g. The procedure and recordkeeping for returning to the initiating pharmacy any prescriptions that are not delivered to the patient; and

h. The procedure for informing the patient and obtaining consent ~~if required by law~~ for using such a dispensing and delivery process.

3. Drugs waiting to be picked up at or delivered from the second pharmacy shall be stored in accordance with subsection A of 18VAC110-20-200.

C. Delivery to a practitioner of the healing arts licensed by the board to practice pharmacy or to sell controlled substances or other authorized person or entity holding a controlled substances registration authorized for this purpose.

1. A prescription may be delivered by a pharmacy to the office of such a practitioner or other authorized person provided there is a written contract or agreement between the two parties describing the procedures for such a delivery system and the responsibilities of each party.

2. Each pharmacy using this delivery system shall maintain a policy and procedure manual that includes the following information:

a. Procedure for tracking and assuring security, accountability, integrity, and accuracy of delivery for the dispensed prescription from the time it leaves the pharmacy until it is handed to the patient or agent of the patient;

b. Procedure for providing counseling;

c. Procedure and recordkeeping for return of any prescription medications not delivered to the patient;

d. The procedure for assuring confidentiality of patient information; and

e. The procedure for informing the patient and obtaining consent ~~if required by law~~ for using such a delivery process.

3. Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in a lockable room or lockable cabinet, cart, or other device that cannot be easily moved and that shall be locked at all times when not in use. Access shall be restricted to the licensed practitioner of the healing arts or the responsible party listed on the application for the controlled substances registration, or either person's designee.

D. The contracts or agreements and the policy and procedure manuals required by this section for alternate delivery shall be maintained both at the originating pharmacy as well as the alternate delivery site.

E. A controlled substances registration as an alternate delivery site shall only be issued to an entity without a prescriber or pharmacist present at all times the site is open, if there is a valid patient health or safety reason not to deliver dispensed prescriptions directly to the patient and if compliance with all requirements for security, policies, and procedures can be reasonably assured.

**18VAC110-20-280. Transmission of a prescription order by facsimile machine.**

A. Prescription orders for Schedule III through VI drugs may be transmitted to pharmacies by facsimile device (FAX) upon the following conditions:

1. The prescription shall be faxed only to the pharmacy of the patient's choice.

2. A valid faxed prescription shall contain all required information for a prescription. A written prescription shall include the prescriber's signature.

3. An authorized agent, as defined in §54.1-3408.01 D of the Code of Virginia, may transmit an oral prescription by facsimile and shall record on the faxed prescription the agent's full name and wording that clearly indicates that the prescription being transmitted is an oral prescription.

4. A faxed prescription shall be valid only if faxed from the prescriber's practice location, except in the following situations:

a. ~~for forwarding~~ Forwarding a faxed chart order from a long term care facility or from a hospice, including a home hospice;

b. Faxing an oral prescription by authorized agent under the conditions set forth in subsection A 2 of this section; or

c. Forwarding a written prescription by an authorized agent from a long term care facility, provided the provider pharmacy maintains written procedures for such transactions, and provided the original prescription is obtained by the provider pharmacy within seven days of dispensing. The original prescription shall be attached to the faxed copy.

5. The following additional information shall be recorded on the faxed prescription:

a. The date that the prescription was faxed;

b. The printed name, address, phone number, and fax number of the authorized prescriber; and

c. The institution, if applicable, from which the prescription was faxed, including address, phone number and fax number.

B. Prescription orders for Schedule II drugs may only be faxed for information purposes and may not serve as the original written prescription authorizing dispensing, except for orders to be administered to ~~nursing home~~ long term care facility and home infusion patients in accordance with §54.1-3408.01 ~~C~~ B of the Code of Virginia and except for prescriptions written for a Schedule II narcotic substance for patients residing in a hospice certified by Medicare under Title XVIII or licensed by the state, which may include home hospice. The prescriber shall note on the prescription if the patient is a hospice patient, and the prescription shall meet all requirements for a written prescription, including the prescriber's signature.

C. If the faxed prescription is of such quality that the print will fade and not remain legible for the required retention period, the receiving pharmacist shall copy or transcribe the faxed prescription on paper of permanent quality.

D. Authorizations for refills may be faxed by the prescriber to the pharmacy provided the authorization includes patient name, address, drug name and strength, quantity, directions for use, prescriber's name, prescriber's signature or agent's name, and date of authorization.

**18VAC110-20-286. Chart orders for outpatients.**

A chart order may be filled by an outpatient (community/retail) pharmacy for outpatient use provided the following conditions are met:

1. The chart order was written for a patient while in a hospital or long term care facility.

2. The pharmacist has all information necessary to constitute a valid outpatient prescription.

3. The pharmacist in an outpatient setting has direction, either written or obtained verbally, that the chart order is actually intended to be outpatient or discharge prescription orders, and not merely a listing drugs the patient was taking while an inpatient.

4. The orders include some direction related to quantity to be dispensed or authorized duration of the order by which the pharmacist can calculate the authorized quantity using directions for use and duration.

**18VAC110-20-320. Refilling of Schedule III through VI prescriptions.**

A. A prescription for a drug listed in Schedule III, IV, or V shall not be dispensed or refilled more than six months after the date on which such prescription was issued, and no such prescription authorized to be filled may be refilled more than five times.

1. Each refilling of a prescription shall be entered on the back of the prescription or on another record in accordance with §54.1-3412 and 18VAC110-20-255, initialed and dated by the pharmacist as of the date of dispensing. If the pharmacist merely initials and dates the prescription, it shall be presumed that the entire quantity ordered was dispensed.

2. The partial dispensing of a prescription for a drug listed in Schedule III, IV, or V is permissible, provided that:

a. Each partial dispensing is recorded in the same manner as a refilling;

b. The total quantity of drug dispensed in all partial dispensing does not exceed the total quantity prescribed; and

c. No dispensing occurs after six months after the date on which the prescription order was issued.

B. A prescription for a drug listed in Schedule VI shall be refilled only as expressly authorized by the practitioner. If no such authorization is given, the prescription shall not be refilled, except as provided in §54.1-3410 C or subdivision 4 of §54.1-3411 of the Code of Virginia.

A prescription for a Schedule VI drug or device shall not be dispensed or refilled more than one year after the date on which it was issued unless the prescriber specifically authorizes dispensing or refilling for a longer period of time not to exceed two years.

C. As an alternative to all manual recordkeeping requirements provided for in subsections A and B of this section, an automated data processing system as provided in 18VAC110-20-250 may be used for the storage and retrieval of all or part of dispensing information for prescription drugs dispensed.

D. ~~Authorized refills of all prescription drugs may only be dispensed in~~ The timing of dispensing an authorized refill of a prescription shall be within reasonable conformity with the directions for use as indicated by the practitioner; if directions have not been provided, then any authorized refills may only be dispensed in reasonable conformity with the recommended dosage and with the exercise of sound professional judgment. An authorized refill may be dispensed early provided the pharmacist documents a valid reason for the necessity of the early refill.

Part VIII

Labeling and Packaging Standards for Prescriptions

**18VAC110-20-340. Packaging standards for dispensed prescriptions.**

A. A drug shall be dispensed only in packaging approved by the current U.S.P.-N.F. for that drug. In the absence of such packaging standard for that drug, it shall be dispensed in a well-closed container.

B. Drugs may be dispensed in compliance packaging for self-administration when requested by the patient or for use in hospitals or long-term care facilities provided that such packaging meets all current U.S.P.-N.F. standards for packaging, labeling and record keeping. Compliance packaging that is comprised of a series of individual containers or pockets labeled with the specific date and time when the contents of that container are to be taken, and which may contain more than one different drug, shall comply with USP-NF standards for customized patient medication packages to include:

1. If the packaging allows for the separation of the individual containers, the labels for each individual container shall be labeled with the identity of each of the drug products contained within;

2. The main packaging label shall contain all the required elements for any outpatient prescription label and shall contain a physical description identifying each solid dosage form contained within the individual containers.

**18VAC110-20-350. Special packaging.**

A. Each drug dispensed to a person in a household shall be dispensed in special packaging except when otherwise directed in a prescription by a practitioner, when otherwise requested by the purchaser, or when such drug is exempted from 16 CFR §1702.1 et seq. promulgated pursuant to the Poison Prevention Packaging Act of 1970 (15 USC §§1471-1476).

B. ~~Each pharmacy may have a sign posted near the prescription department advising the patients that nonspecial packaging may be requested.~~

~~C.~~ If nonspecial packaging is requested, a notation will be made on the dispensing record or other retrievable record ~~a release of such request shall be obtained from the patient or the patient's authorized agent and maintained for two years from the date of dispensing~~.

**18VAC110-20-355. Pharmacy repackaging of drug; records required; labeling requirements.**

A. Pharmacies in which bulk reconstitution of injectable, bulk compounding or the repackaging or prepackaging of drugs is performed shall maintain adequate control records for a period of one year or until the expiration, whichever is greater. The records shall show the name of the drug(s) used; strength, if any; date repackaged; quantity prepared; initials of the pharmacist verifying the process; the assigned lot or control number; the manufacturer's or distributor's name and lot or control number; and an expiration date.

B. The drug name; strength, if any; the assigned lot or control number or the manufacturer's or distributor's name and lot or control number; and an appropriate expiration date determined by the pharmacist in accordance with USP guidelines shall appear on any subsequently repackaged or reconstituted units.

C. Pharmacies using automated counting devices or dispensers in which drugs are removed from manufacturer's original packaging and placed in bulk bins shall comply with the following requirements:

1. A bin filling record shall be maintained, manually or in a computerized record for a period of one year from date of filling from which information can be readily retrieved, for each bin including:

a. The drug name and strength, if any;

b. The name of the manufacturer or distributor;

c. Manufacturer's control or lot number(s) and expiration date for all lots placed into the bin at the time of filling;

d. Any assigned lot number; ~~and~~

e. An expiration date determined according to USP guidelines for repackaging;



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f. The date of filling; and

g. The pharmacist's initials verifying the accuracy of the process.

2. If more than one lot is added to a bin at the same time, the lot which expires first shall be used to determine the expiration date if shorter than a calculated date based on USP guidelines.

3. Each bin shall be labeled in such a manner as to cross-reference the information on the filling record with the correct expiration date.

4. If only one lot is added to a bin at one time, but a ~~second~~ subsequent lot may be added before the first has cleared, the automated device shall be constructed to reasonably dispense the first lot before the second lot is dispensed, the expiration date on the bin's label shall reflect the expiration date assigned to the earlier lot, and the bin shall be allowed to "run dry" where all product is completely removed prior to filling at least once every 60 days with a record made of the run dry dates.

D. A pharmacy may return a dispensed drug to stock for re-dispensing that has never left the pharmacy premises or the control of the pharmacy delivery agent pursuant to §54.1-3411.1 A 3 under the following conditions:

1. An expiration date shall be placed on the label prior to returning the drug to stock. In the absence of stability data to the contrary, the date on the label may not exceed the expiration date on the manufacturer's container or one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier.

2. The restocked drug shall be used to fill the next prescription received for that product. In the event that the drug is not dispensed prior to the new assigned expiration date, it shall be removed from working stock as expired, and disposed of in accordance with 18VAC110-20-210.

3. If there is no lot number on the label of a drug returned to stock or on the prescription records which can be cross-referenced from the prescription label, the drug shall be removed from stock upon any recall of that drug product and returned to the manufacturer or otherwise disposed of in accordance with 18VAC110-20-210.

## Part IX

## Standards for Prescription Transactions

### 18VAC110-20-391. Prescription blanks.

If a pharmacy provides prescription blanks to prescribers, no advertising or other information shall be on the face of the prescription blank other than prompts for essential information required by law to be on a written prescription. Any nonessential information such as coupons or pharmacy name may be placed on the back of the prescription blank or on a separate sheet of paper, but shall not be on or attached to the face of the blank.

### 18VAC110-20-395. Purchase of drugs.

Except for an emergency purchase from another pharmacy, a pharmacist may only purchase Schedule II through VI drugs from a wholesale distributor or warehouser licensed or registered by the board.

### 18VAC110-20-410. Permitted physician licensed by the board.

A. Pursuant to §54.1-3304 of the Code of Virginia, physicians licensed by the board to dispense drugs, when pharmacy services are not reasonably available, shall be subject to the following sections of this chapter. For purposes of this section, the terms "pharmacist," "pharmacist-in-charge," "pharmacy", and "PIC" in the following shall be deemed to mean the physician permitted by the board:

1. 18VAC110-20-110 C and D;

2. 18VAC110-20-130 A;

3. 18VAC110-20-140 A and C;

4. 18VAC110-20-150 except that these requirements shall not apply to physicians licensed prior to August 25, 2004, unless the dispensing area is relocated or remodeled;

5. 18VAC110-20-160;

6. 18VAC110-20-180;

7. 18VAC110-20-190 A, B and C;

8. 18VAC110-20-200;

9. 18VAC110-20-210; and

10. 18VAC110-20-240 through 18VAC110-20-410.

B. A physician may apply for a special or limited use permit in accordance with 18VAC110-20-120.

Part X

Compounding Sterile Pharmaceutical Products

**18VAC110-20-425. Robotic ~~Pharmacy Systems~~ pharmacy systems.**

A. A pharmacy providing services to a hospital or a long-term care facility using a unit dose dispensing system may ~~apply for approval of~~ operate a robotic pharmacy system dispensing unit dose, bar-coded drugs ~~and a waiver of 18VAC110-20-270 B~~, and is exempted from 18VAC110-20-270 C, provided the accuracy of the final dispensed prescription product complies with ~~is determined by~~ a written quality assurance plan and requirements of this chapter. ~~An applicant shall apply using a form provided by the board and shall pay a fee as set forth in 18VAC110-20-20.~~ The following requirements for operation of a robotic pharmacy system shall apply:

1. Pharmacists shall review for accuracy and appropriateness of therapy all data entry of prescription orders into the computer operating the system.

2. The packaging, repackaging, stocking and restocking of the robotic pharmacy system shall be performed by pharmacy technicians or pharmacists.

3. Pharmacists shall verify and check for the accuracy of all drugs packaged or repackaged for use by the robot by a visual check of both labeling and contents prior to stocking the drugs in the robotic pharmacy system. A repackaging record shall be maintained in accordance with 18VAC110-20-355 A, and the verifying pharmacist shall initial the record. Packaging and labeling, including the appropriate beyond-use date, shall conform to requirements of this chapter and current USP-NF standards.

4. A written policy and procedure must be maintained and shall include at a minimum, procedures for ensuring:

a. Accurate packaging and repackaging of all drugs for use in the robotic pharmacy system, to include properly labeled barcodes, and method for ensuring pharmacist verification of all packaged and repacked drugs compliant with this chapter;

b. Accurate stocking and restocking of the robotic pharmacy system;

c. Removing expired drugs;

d. Proper handling of drugs which may be dropped by the robotic pharmacy system;

e. Performing routine maintenance of robotic pharmacy system as indicated by manufacturer's schedules and recommendations;

f. Accurate dispensing of drugs via robotic pharmacy system for cart fills, first doses, and cart fill updates during normal operation and during any scheduled or unscheduled downtime;

g. Appropriately investigating, identifying and correcting sources of discrepancies or errors associated with the robotic pharmacy system; and

h. Maintaining quality assurance reports.

5. Pharmacists shall perform a daily random check of medications picked by the robot for 5% of all patients' bins and 5% of all first doses or cart updates. Documentation of this check shall include the pharmacist's initials for each medication checked and a description of all discrepancies found.

6. All manual picks shall be checked by pharmacists.

7. If the robot picks an incorrect medication, the pharmacy shall immediately institute a 100% check of all patients' bins or doses and shall immediately report the error to the board. The 100% check procedure shall continue until such time as the pharmacy provides documentation to the

board showing that the cause of the error has been determined and addressed and that the robot is no longer making errors, and the board allows the pharmacy to return to a reduction in checking.

8. Quarterly quality assurance reports demonstrating the accuracy of the robot shall be maintained. At a minimum, these reports shall include:

a. A summary indicating the date and description of all discrepancies that include but are not limited to discrepancies involving the packaging, repackaging and dispensing of drugs via the robotic pharmacy system, found during that quarter plus a cumulative summary since initiation of the robotic pharmacy system.

b. The total number of doses packaged for the robotic pharmacy system and total number of doses picked by the robot during the quarter.

c. The total number of doses picked by the robot that were checked in conducting the 5% patient bin check, 5% cart updates check, and 5% first dose check.

d. Dates and time associated with any scheduled or unanticipated downtime with an explanation of the problem to include the time span of the downtime and the resolution.

9. All unanticipated downtime shall be immediately reported to the board.

10. All records required by this section shall be maintained at the address of the pharmacy for a minimum of two years. Records may be maintained in offsite storage or as an electronic image which provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

~~B. A copy of the quality assurance plan shall be submitted as a part of the application and shall include at a minimum the following:~~

~~1. Method of ensuring accurate packaging and loading of the robotic pharmacy system.~~

~~2. Procedures for conducting quality control checks of final dispensing for accuracy.~~

~~3. Manufacturer's schedules and recommendations for maintenance of the device.~~

~~4. Plan for maintenance of all related documentation for a minimum of two years.~~

~~C. The application shall be reviewed by an informal conference committee of the board, consisting of no less than two members of the board.~~

~~1. The informal conference committee may approve or deny the application, or may approve the application upon terms and conditions.~~

~~2. The committee may require an inspection of a new or modified robotic pharmacy system prior to approval.~~

~~3. The committee may require that periodic reports be submitted detailing frequency and types of errors determined by the continuous quality assurance checks.~~

~~4. The board may withdraw the approval of a waiver for failure to comply with the quality assurance plan or with other terms and conditions which have been established by the board.~~

~~D. The board shall be notified prior to implementing any modification to the approved application and no modification may be implemented until approved by the board.~~

~~E. If a robotic pharmacy system is used, a pharmacist shall review all data entry of prescription orders into the computer operating the system for accuracy and appropriateness of therapy and shall check all repackaged medication prior to use in loading the system.~~

**18VAC110-20-440. Responsibilities of the pharmacist-in-charge.**

A. The PIC in a pharmacy located within a hospital or the PIC of any outside pharmacy providing pharmacy services to a hospital shall be responsible for establishing procedures for and assuring maintenance of the proper storage, security, and dispensing of all drugs used throughout the hospital.

B. The PIC of a pharmacy serving a hospital shall be responsible for maintaining a policy and procedure for providing reviews of drug therapy to include at a minimum any irregularities in drug therapy consistent with §54.1-3319 A of the Code of Virginia ~~to include at a minimum any~~

~~irregularities in drug therapy, drug interactions, drug administration, or transcription errors. All significant irregularities shall be brought to the attention of the attending practitioner or other person having authority to correct the potential problem.~~

C. Prior to the opening of a satellite pharmacy within the hospital, the PIC shall notify the board as required by 18VAC110-20-140 and shall ensure compliance with subsections B through G of 18VAC110-20-150, 18VAC110-20-160, 18VAC110-20-170, 18VAC110-20-180 and 18VAC110-20-190. No drugs shall be stocked in a satellite pharmacy until an inspection has been completed and approval given for opening.

D. For the following list of Schedule VI controlled substances, the PIC of a pharmacy serving a hospital may authorize the storage in an area of the hospital outside the pharmacy, and may delegate the ordering and distribution within the hospital to nonpharmacy personnel provided the conditions for proper storage and adequate security and the procedures for distribution are set forth in the pharmacy's policy and procedure manual, and provided that the PIC assures that these storage areas are checked monthly for compliance. The storage areas must be locked when authorized staff is not present in the area. Except for nitrous oxide, medical gases may be stored in an unlocked area.

1. Large volume parenteral solutions that contain no active therapeutic drugs other than electrolytes;

2. Irrigation solutions;

3. Contrast media;

4. Medical gases;

5. Sterile sealed surgical trays that may include a Schedule VI drug; and

6. Blood components and derivatives, and synthetic blood components and products that are classified as prescription drugs.

**18VAC110-20-450. After-hours access to the pharmacy.**

A. When authorized by the PIC, an authorized nurse may have access to ~~the pharmacy in the absence of the pharmacist~~ a supply of drugs maintained by the pharmacy at a location outside the pharmacy in order to obtain emergency medication during hours the pharmacy is closed, provided that such drug is available in the manufacturer's original package or in units which have been prepared and labeled by a pharmacist and provided further that a separate record shall be made and left ~~within the pharmacy~~ at the location of the stock of drugs on a form prescribed by the PIC and such records are maintained within the pharmacy for a period of one year showing:

1 The date of withdrawal;

2. The patient's name;

3. The name of the drug, strength, dosage form and dose prescribed;

4. Number of doses removed; and

5. The signature of the authorized nurse.

B. If the after-hours supply of drugs is in an area that is continuously open and staffed, such as a patient floor or emergency room, then the area does not need to be alarmed. If the after-hours supply is maintained in an area of the hospital that is not open and continuously staffed, such as a floor that primarily houses departments that are closed daily, then an alarm that meets the requirements of 18VAC110-20-180 shall be installed and activated at all times.

**18VAC110-20-460. Floor stock drugs; proof of delivery; distribution records.**

A. A pharmacist shall check all Schedule II-VI drugs delivered to a hospital unit as floor-stock before the drugs leave the pharmacy and shall initial or sign manually or electronically the record of distribution verifying the accuracy of the distribution.

B. A delivery receipt shall be obtained for Schedule II through V drugs supplied as floor stock. This record shall include the date, drug name and strength, quantity, hospital unit receiving drug and the manual or electronic signatures of the dispensing pharmacist and the receiving nurse. ~~Receipts shall be maintained in the pharmacy for a period of two years or in offsite storage which shall be~~

~~retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.~~

~~B.~~C. A record of disposition/administration shall be used to document administration of Schedule II through V drugs when a floor stock system is used for such drugs. The record shall be returned to the pharmacy within three months of its issue. The PIC or his designee shall:

1. Match returned records with delivery receipts to verify that all records are returned;

2. Periodically audit returned administration records for completeness as to patient's names, dose, date and time of administration, signature or initials of person administering the drug, and date the record is returned;

3. Verify that all additions to inventory are recorded, that all additions to and deductions from inventory are correctly calculated, that sums carried from one record to the next are correctly recorded, and periodically verify that doses documented on administration records are reflected in the medical record; and

4. Initial the returned record~~, file chronologically by date of issue, and retain for two years from the date of return or in offsite storage which shall be retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent~~.

~~C.~~D. All records required by this section shall be filed chronologically by date of issue, and retained for two years from the date of return at the address of the pharmacy. Schedule VI records may be maintained in offsite storage or as an electronic image which provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent. Schedule II-V records may only be stored offsite or electronically as described above if authorized by DEA or in federal law or regulation. The filing requirements of 18VAC110-20-240 A 1 for separation of Schedule II records shall be met for administration records if the Schedule II drugs are listed in a separate section on a page that contains other schedules of drugs.

**18VAC110-20-490. Automated devices for dispensing and administration of drugs.**

A hospital may use automated devices for the dispensing and administration of drugs pursuant to §54.1-3301 of the Code of Virginia and §§54.3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420 or 18VAC110-20-460 as applicable. The following conditions shall apply:

1. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device which shall include the date; drug name, dosage form, and strength; quantity; hospital unit and a unique identifier for the specific device receiving the drug; initials of the person loading the automated dispensing device; and initials of the pharmacist ~~reviewing the transaction~~ checking the drugs to be removed from the pharmacy and the delivery record for accuracy.

2. At the time of loading, the delivery record for all Schedule II through V drugs shall be signed by a nurse or other person authorized to administer drugs from that specific device, and the record returned to the pharmacy ~~and maintained in chronological order for a period of two years from date of delivery. The delivery record and required signatures may be generated or maintained electronically provided the system being used has the capability of recording an electronic signature which is a unique identifier and restricted to the individual receiving the drugs and provided that this record is maintained in a "read-only" format which cannot be altered after the information is recorded. The electronic record shall be readily retrievable, maintained for a period of two years, and the system used shall be capable of producing a hard-copy printout of the record upon request~~.

3. At the time of loading any Schedule II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the pharmacist in charge, who shall be responsible for reconciliation of the discrepancy or properly reporting of a loss.

4. Automated dispensing devices in hospitals shall be capable of producing a hard-copy record of distribution which shall show patient name, drug name and strength, dose withdrawn, dose to be

administered, date and time of withdrawal from the device, and identity of person withdrawing the drug.

5. The PIC or his designee shall conduct at least a monthly audit to review distribution and administration of Schedule II through V drugs from each automated dispensing device as follows:

a. The audit shall reconcile records of all quantities of Schedule II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.

b. A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with §54.1-3404 E of the Drug Control Act.

c. The audit shall include a review of a sample of administration records from each device per month for possible diversion by fraudulent charting. A sample ~~from each device shall not be less than 24 consecutive hours within the month being audited~~shall include all Schedule II-V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

d. The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered.

e. The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper recordkeeping.

f. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit ~~and maintained in the pharmacy for a period of two years~~. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record. ~~These distribution records reviewed in conducting the audit may be maintained electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format which does not allow alteration of the records; and provided a log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.~~

6. If an automated dispensing device is used to obtain drugs for dispensing from an emergency room, a separate dispensing record is not required provided the automated record distinguishes dispensing from administration and records the identity of the physician who is dispensing.

7. Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes.

8. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device.

9. Proper use of the automated dispensing devices and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual.

10. All records required by this section shall be filed in chronological order from date of issue and maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the hospital except:

a. Manual Schedule VI distribution records may be maintained in offsite storage; or electronically as an electronic image which provides an exact image of the document that is clearly legible provided such offsite or electronic records are retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.



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b. Distribution and delivery records and required signatures may be generated or maintained electronically provided

(1) The system being used has the capability of recording an electronic signature which is a unique identifier and restricted to the individual required to initial or sign the record

(2) The records are maintained in a read-only format which cannot be altered after the information is recorded

(3) The system used is capable of producing a hard-copy printout of the records upon request.

c. Schedule II-V distribution and delivery records may only be stored offsite or electronically as described above if authorized by DEA or in federal law or regulation.

d. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained at an off-site location or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format which does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

**18VAC110-20-500. Licensed emergency medical services agencies program.**

The pharmacy may prepare a drug kit for a licensed emergency medical services agency provided:

1. The PIC of the hospital pharmacy shall be responsible for all ~~controlled~~ prescription drugs contained in this drug kit. A pharmacist shall check each drug kit after filling the kit, and initial the filling record certifying the accuracy and integrity of the contents of the kit.

2. The drug kit is sealed in such a manner that it will ~~preclude any possibility of~~ deter theft or loss of drugs and aid in detection of such.

3. Drugs may be administered by an emergency medical technician upon an oral order or written standing order of an authorized medical practitioner in accordance with §54.1-3408 of the Code of Virginia. Oral orders shall be reduced to writing by the technician and shall be signed by a medical practitioner. Written standing orders shall be signed by the operational medical director for the emergency medical services agency. The emergency medical technician shall make a record of all drugs administered to a patient. This administration record shall be signed by the medical practitioner who assumes responsibility for the patient at the hospital. If the patient is not transported to the hospital or if the attending medical practitioner at the hospital refuses to sign the record, a copy of this record shall be signed and placed in delivery to the hospital pharmacy who was responsible for that kit exchange by the agency's operational medical director within seven days of the administration.

4. When the drug kit has been opened, the kit shall be returned to the pharmacy and exchanged for an unopened kit. The record of the drugs administered shall accompany the opened kit when exchanged. An accurate record shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year.

5. The record of the drugs administered shall be maintained as a part of the pharmacy records pursuant to state and federal regulations for a period of not less than two years.

6. Intravenous solutions provided by a hospital pharmacy to an emergency medical services agency, may be stored separately outside the drug kit.

**18VAC110-20-520. Drugs in long-term care facilities.**

~~Drugs~~ Prescription drugs, as defined in the Drug Control Act, shall not be floor stocked by a long-term care facility, except those in the stat drug box or emergency drug box or as provided for in 18VAC110-20-560 within this chapter.

**18VAC110-20-530. Pharmacy's responsibilities to long-term care facilities.**

The pharmacy serving a long-term care facility shall:

1. Receive a valid order prior to the dispensing of any drug.

2. Ensure that personnel administering the drugs are trained in using the dispensing system provided by the pharmacy.

3. Ensure that the drugs for each patient are kept and stored in the originally received containers and that the medication of one patient shall not be transferred to another patient.

4. Ensure that each cabinet, cart or other area utilized for the storage of drugs is locked and accessible only to authorized personnel.

5. Ensure that the storage area for patients drugs is well lighted, of sufficient size to permit storage without crowding, and is maintained at appropriate temperature.

6. Ensure that poison and drugs for "external use only" are kept in a cabinet and separate from other medications.

7. Provide for the disposition of discontinued drugs under the following conditions:

a. Discontinued drugs may be returned to the pharmacy for resale or transferred to another pharmacy for redispensing to the indigent if authorized by §54.1-3411.1 and 18VAC110-20-400, or ~~destroyed~~ disposed of by appropriate means in compliance with 18VAC110-20-210 and with any applicable local, state, and federal laws and regulations.

b. Drug destruction at the pharmacy shall be witnessed by the PIC and by another pharmacy employee. The pharmacy may transfer the drugs for destruction to an entity appropriately licensed to accept returns for destruction. Drug destruction at the facility shall be witnessed by the director of nursing or, if there is no director, then by the facility administrator and by a pharmacist providing pharmacy services to the facility or by another employee authorized to administer medication.

c. A complete and accurate record of the drugs returned or destroyed or both shall be made. The original of the record of destruction shall be signed and dated by the persons witnessing the destruction and maintained at the long-term care facility for a period of two years. A copy of the destruction record shall be maintained at the provider pharmacy for a period of two years.

d. Long-term care facilities shall destroy discontinued or unused drugs or return them to the pharmacy without 30 days of the date the drug was discontinued.

8. Ensure that appropriate drug reference materials are available in the facility units.

9. Ensure that a monthly review of drug therapy by a pharmacist is conducted for each patient in long-term care facilities except those licensed under Title 63.1 of the Code of Virginia. Such review shall be used to determine any irregularities, which may include but not be limited to drug therapy, drug interactions, drug administration or transcription errors. The pharmacist shall sign and date the notation of the review. All significant irregularities shall be brought to the attention of the attending practitioner or other party having authority to correct the potential problem.

**18VAC110-20-535. Repackaging of already dispensed prescriptions.**

The primary provider pharmacy for a long term care facility may, but shall not be required to, repackage a resident's prescription drugs, dispensed by another pharmacy, into the unit-dose or compliance packaging system used by the long term care facility to assist in maintaining a uniform or more accurate system of administration.

1. Such repackaging shall only be done at the provider pharmacy.

2. Unit dose repackaging shall comply with requirements of 18VAC110-20-420 and compliance packaging shall comply with 18VAC110-20-340 B.

3. Records shall be maintained of all such repackaging of previously dispensed medications to include date; repackaging pharmacist's initials (or those of the checking pharmacist); and the pharmacy name, address, and prescription number of the original dispensing.

4. Any portion of a resident's medication not placed into unit dose or compliance packaging may be returned to the resident or kept for subsequent repackaging at the provider pharmacy in the original labeled container. If kept at the pharmacy, it shall be stored within the prescription



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department but separate from any working stock of drugs used for dispensing by the pharmacy, and shall only be used for the patient to whom the medication was originally dispensed.

**18VAC110-20-536. Prescription drugs sent outside the facility.**

A. The provider pharmacy shall assure that residents who leave a long term care facility for short periods of time or are discharged and who are allowed to take dispensed prescription medications with them, do so only in appropriate packaging, properly labeled for outpatient use.

B. Pharmacies that provide medication to residents, in compliance packaging that meets the requirements of 18VAC110-20-340 B, shall assure that if the facility separates and sends only the individual containers needed during the time the resident is away without the main package label, that the resident is also given a copy of the main package label or other appropriate documentation that contains the complete labeling information on the main package label.

**18VAC110-20-540. Emergency drug kit.**

The pharmacist providing services may prepare an emergency kit for a long term care facility in which access to the kit is restricted to a licensed nurse, pharmacist, or prescriber and only these licensed individuals may administer a drug taken from the kit and only ~~only those persons licensed to administer are administering drugs~~ under the following conditions:

1. The contents of the emergency kit shall be of such a nature that the absence of the drugs would threaten the survival of the patients.

2. The contents of the kit shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the institutions and shall be limited to drugs for administration by injection or inhalation only, except that Nitroglycerin SL may be included.

3. The kit is sealed in such a manner that it will preclude any possible loss of the drug.

a. The dispensing pharmacy must have a method of sealing such kits so that once the seal is broken, it cannot be reasonably resealed without the breach being detected.

b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication and/or resealing. The pharmacy shall maintain a record of the seal identifiers when placed on a box or kit and maintain the record until such time as the seal is replaced.

c. In lieu of seals, a kit with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy is also acceptable.

4. The kit shall have a form to be filled out upon opening the kit and removing contents to write the name of the person opening the kit, the date, time and name and quantity of item(s) removed. The opened kit is maintained under secure conditions and returned to the pharmacy within 72 hours for replenishing.

5. Any drug used from the kit shall be covered by a prescription, signed by the prescriber, when legally required, within 72 hours.

**18VAC110-20-550. Stat-drug box.**

An additional drug box called a stat-drug box may be prepared by a pharmacy to provide for initiating therapy prior to the receipt of ordered drugs from the pharmacy. Access to the stat-drug box is restricted to a licensed nurse, pharmacist, or prescriber and only these licensed individuals may administer a drug taken from the stat-drug box. Additionally, a valid prescription or lawful order of a prescriber must exist prior to the removal of any drug from the stat-drug box. A stat-drug box ~~shall be provided to those facilities in which only those persons licensed to administer are administering drugs and~~ shall be subject to the following conditions:

1. The box is sealed in such a manner that will preclude the loss of drugs.

a. The dispensing pharmacy must have a method of sealing such boxes so that once the seal is broken, it cannot be reasonably resealed without the breach being detected.

b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication or resealing, or both. The pharmacy shall maintain a record of the seal

identifiers when placed on a box and maintain the record until such time as the seal is replaced.

c. In lieu of seals, a box with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy is also acceptable.

2. The box shall have a form to be filled out upon opening the box and removing contents to write the name of the person opening the box, the date, time and name and quantity of item(s) removed. When the stat-drug box has been opened, it is returned to the pharmacy.

3. ~~Any drug used from the box shall be covered by a drug order signed by the prescriber, when legally required, within 72 hours.~~

~~4.~~ There shall be a listing of the contents of the box maintained in the pharmacy and also attached to the box in the facility. This same listing shall become a part of the policy and procedure manual of the facility served by the pharmacy.

~~5.~~4. The drug listing on the box shall bear an expiration date for the box. The expiration date shall be the day on which the first drug in the box will expire.

~~6.~~5. The contents of the box shall be limited to those drugs in which a delay in initiating therapy may result in harm to the patient.

a. The listing of drugs contained in the stat-drug box shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the long-term care facility.

b. The stat-drug box shall contain no Schedule II drugs.

c. The stat-drug box shall contain no more than one Schedule III through V drug in each therapeutic class and no more than five doses of each.

**18VAC110-20-555. Use of automated dispensing devices.**

Nursing homes licensed pursuant to Chapter 5 (§32.1-123 et seq.) of Title 32.1 of the Code of Virginia may use automated drug dispensing systems, as defined in §54.1-3401 of the Code of Virginia, upon meeting the following conditions:

1. Drugs placed in an automated drug dispensing system in a nursing home shall be under the control of the pharmacy providing services to the nursing home, the pharmacy shall have on-line communication with and control of the automated drug dispensing system, and access to any drug for a patient shall be controlled by the pharmacy.

2. A nursing home without an in-house pharmacy shall obtain a controlled substances registration prior to using an automated dispensing system.

3. Removal of drugs from any automated drug dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber~~.~~ under the following conditions:

a. A drug may not be administered to a patient from an automated dispensing device until a pharmacist has reviewed the prescription order and electronically authorized the access of that drug for that particular patient in accordance with the order.

b. The PIC of the provider pharmacy shall ensure that a pharmacist who has on-line access to the system is available at all times to review a prescription order as needed and authorize administering pursuant to the order reviewed.

c. Drugs that would be stocked in an emergency drug kit pursuant to 18VAC110-20-540 may be accessed prior to receiving electronic authorization from the pharmacist provided that the absence of the drugs would threaten the survival of the patients.

d. Automated dispensing devices shall be capable of producing a hard-copy record of distribution which shall show patient name, drug name and strength, dose withdrawn, dose to be administered, date and time of withdrawal from the device, and identity of person withdrawing the drug.

4. Drugs placed in automated dispensing devices shall be in the manufacturer's sealed original unit dose or unit-of-use packaging or in repackaged unit-dose containers in compliance with the requirements of 18VAC110-20-355 relating to repackaging, labeling, and records.

5. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device which shall include the date; drug name, dosage form, and strength; quantity; nursing home; and a unique identifier for the specific device receiving drugs; and initials of pharmacist checking the order of drugs to be removed from the pharmacy and the records of distribution for accuracy.

6. At the direction of the PIC, drugs may be loaded in the device by a pharmacist or a pharmacy technician adequately trained in the proper loading of the system.

7. At the time of loading, the delivery record for all Schedule II through ~~V~~ VI drugs shall be signed by a nurse or other person authorized to administer drugs from that specific device, and the record returned to the pharmacy ~~and maintained in chronological order for a period of two years from date of delivery. The delivery record and required signatures may be generated or maintained electronically provided the system being used has the capability of recording an electronic "signature" which is a unique identifier and restricted to the individual receiving the drugs and provided that this record is maintained in a "read-only" format which cannot be altered after the information is recorded. The electronic record shall be readily retrievable, maintained for a period of two years, and the system used shall be capable of producing a hard copy printout of the record upon request~~.

8. At the time of loading any Schedule II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the PIC, who shall be responsible for reconciliation of the discrepancy or properly reporting of a loss.

9. The PIC or his designee shall conduct at least a monthly audit to review distribution and administration of Schedule II through V drugs from each automated dispensing device as follows:

a. The audit shall reconcile records of all quantities of Schedule II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.

b. A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

c. The audit shall include a review of a sample of administration records from each device per month for possible diversion by fraudulent charting. A sample ~~from each device shall not be less than 24 consecutive hours within the month being audited~~ shall include all Schedule II-V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

d. The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered.

e. The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper recordkeeping.

f. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit ~~and maintained in the pharmacy for a period of two years~~. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record. ~~These distribution records reviewed in conducting the audit may be maintained electronically provided they can be readily retrieved upon request; provided they are maintained in a "read-only' format which does not allow alteration of the records; and provided a log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, initials of all reviewers.~~

10. Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes.

11. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device.

12. The PIC of the pharmacy providing services to the nursing home shall establish, maintain, and assure compliance with written policy and procedure for the accurate stocking and proper storage of drugs in the automated drug dispensing system, accountability for and security of all drugs maintained in the automated drug dispensing system, preventing unauthorized access to the system, tracking access to the system, complying with federal and state regulations related to the storage and dispensing of controlled substances, maintaining patient confidentiality, maintaining required records, and assuring compliance with the requirements of this chapter. The manual shall be capable of being accessed at both the pharmacy and the nursing home.

13. All records required by this section shall be filed in chronological order from date of issue and maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the nursing home except:

a. Manual Schedule VI distribution records may be maintained in offsite storage; or electronically as an electronic image which provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

b. Distribution and delivery records and required signatures may be generated or maintained electronically provided

(1) the system being used has the capability of recording an electronic signature which is a unique identifier and restricted to the individual required to initial or sign the record

(2) the records are maintained in a read-only format which cannot be altered after the information is recorded

(3) the system used is capable of producing a hard-copy printout of the records upon request.

c. Schedule II-V distribution and delivery records may only be stored offsite or electronically as described above if authorized by DEA or in federal law or regulation.

d. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained off site or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format which does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

**18VAC110-20-570. Drugs in infirmaries/first aid rooms.**

A. ~~Controlled~~ Prescription drugs purchased by an institution, agency, or business within the Commonwealth, having been purchased in the name of a practitioner licensed by the Commonwealth of Virginia and who is employed by an institution, agency, or business which does not hold a pharmacy permit, shall be used only for administering to those persons at that institution, agency, or business.

B. All ~~controlled~~ prescription drugs shall be maintained and secured in a suitable locked storage area, the key to which will be in the possession of the practitioner or nurse who is under the direction and supervision of the practitioner.

C. Such institution, agency, or business shall adopt a specific protocol for the administration of prescription drugs, listing the inventory of such drugs maintained, and authorizing the administering of such drugs in the absence of a practitioner in an emergency situation when the timely prior verbal or written order of a prescriber is not possible. Administering of such drugs shall be followed by written orders.



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1. For the purpose of this chapter, "emergency" means a circumstance requiring administration of ~~controlled~~ prescription drugs necessary to preserve life or to prevent significant or permanent injury or disability.

2. The protocol shall be maintained for inspection and documentation purposes.

~~D. A nurse may, in the absence of a practitioner, administer and provide nonprescription drugs in unit dose containers in quantities which in the professional judgment of the nurse will maintain the person at an optimal comfort level until the person's personal practitioner can be consulted. The administering and providing of such medication must be in accordance with explicit instructions of a specific protocol promulgated by the practitioner in charge of the institution, agency, or business.~~

**18VAC110-20-580. Humane societies and animal shelters.**

A humane society or animal shelter, after having obtained the proper permits pursuant to state and federal laws, may purchase, possess and administer any drug approved by the State Veterinarian to euthanize injured, sick, homeless and unwanted domestic pets and animals provided that these procedures are followed:

1. Drugs ordered by a humane society for euthanasia shall only be stored and administered at the address of the humane society. Humane societies shall not order or possess a stock of drugs for any purpose other than euthanasia.

~~1.~~2. A veterinarian shall provide general supervision for the facility and shall provide and certify training in accordance with guidelines set forth by the State Veterinarian to the person(s) responsible for administration of the drugs. Certification of training signed by the veterinarian providing the training shall be maintained at the facility for each person administering drugs and must be retained for not less than two years after the person ceases administering.

~~2.~~3. The person in charge of administration of drugs for euthanasia for the facility shall obtain the required permit and controlled substances registration from the board and shall be responsible for maintaining proper security and required records of all controlled substances obtained and administered.

a. If that person ceases employment with the facility or relinquishes his position, he shall immediately return the permit to the board and shall take a complete and accurate inventory of all drugs in stock.

b. An application for a new permit shall be filed with the required fee within 14 days on a form provided by the board. At that time, the new responsible person shall take a complete and accurate inventory of all drugs in stock.

~~3.~~4. Drugs shall be stored in a secure, locked place and only the person(s) responsible for administering may have access to the drugs.

~~4.~~5. Any drug used shall be obtained and administered in the injectable form only.

~~5.~~6. All invoices and order forms shall be maintained for a period of two years.

~~6.~~7. Complete and accurate records shall be maintained for two years on the administration of the drug. The record shall show the name and strength of the drug, date of administration, the species of the animal, the weight of animal, the amount of drug administered and the signature of the person administering the drug.

**18VAC110-20-590. Drugs in correctional ~~institutions~~ facilities.**

A. All prescription drugs at any correctional ~~unit~~ facility shall be obtained only on an individual prescription basis from a pharmacy and subject to the following conditions:

1. All prepared drugs shall be maintained in a suitable locked storage area with only the person responsible for administering the drugs having access.

2. Complete and accurate records shall be maintained of all drugs received, administered and discontinued. The administration record shall show the:

a. Patient name;

b. Drug name and strength;

c. Number of dosage units received;

d. Prescriber's name; and

e. Date, time and signature of the person administering the individual dose of drug.

3. All unused or discontinued drugs shall be sealed and the amount in the container at the time of the sealing shall be recorded on the drug administration record. Such drugs shall be returned to the provider pharmacy or to a secondary pharmacy along with the drug administration record, a copy of the drug administration record, or other form showing substantially the same information, within thirty days of discontinuance.

a. The provider or secondary pharmacy shall conduct random audits of returned drug administration records for accountability.

b. The drug administration records shall be filed in chronological order by the provider or secondary pharmacy and maintained for a period of one year or, at the option of the facility, the records may be returned by the pharmacy to the facility.

c. Drugs may be returned to pharmacy stock in compliance with the provisions of 18VAC110-20-400.

d. Other drugs shall be disposed of or destroyed by the provider pharmacy in accordance with local, state, and federal regulations.

4. Alternatively, drugs for destruction may be forwarded by a pharmacist directly from the correctional facility to a returns company after performing the audit required by subdivision 3 a of this section and ensuring the proper maintenance of the administration records.

B. Emergency and stat-drug box. An emergency box and a stat-drug box may be prepared for ~~the~~ a correctional facility served by the pharmacy pursuant to 18VAC110-20-540 and 18VAC110-20-550 provided that the facility employs one or more full-time physicians, registered nurses, licensed practical nurses, or physician assistants ~~or correctional health assistants~~.

C. Prescription drugs, including but not limited to vaccines, may be floor-stocked only at a medical clinic or surgery center which is part of a correctional facility and which is staffed by one or more ~~physicians~~ prescribers during the hours of operation, provided the clinic first obtains a controlled substances registration and complies with the requirements of 18VAC110-20-690, 18VAC110-20-700, 18VAC110-20-710, and 18VAC110-20-720.

## Part XV

## Exempted Stimulant or Depressant Drugs and Chemical Preparations

### 18VAC110-20-610. Exempted chemical preparations.

The list of exempt chemical preparations ~~set forth in~~ pursuant to 21 CFR §1308.24 and maintained by the administrator of DEA is adopted pursuant to the authority set forth in §§54.1-3443, 54.1-3450 and 54.1-3452 of the Drug Control Act.

### 18VAC110-20-620. Exempted prescription products.

The list of exempt prescription products ~~set forth in~~ pursuant to 21 CFR 1308.32 and maintained by the administrator of DEA is adopted pursuant to the authority set forth in §§54.1-3443, 54.1-3450 and 54.1-3452 of the Drug Control Act; the exempted prescription products are drugs which are subject to the provisions of §54.1-3455 of the Drug Control Act.

### 18VAC110-20-621. Exempted anabolic steroid products.

The list of exempt anabolic steroid products ~~set forth in~~ pursuant to 21 CFR 1308.34 and maintained by the administrator of DEA is adopted pursuant to the authority set forth in §§54.1-3443, 54.1-3450 and 54.1-3452 of the Drug Control Act; the exempted anabolic steroid products are drugs which are subject to the provisions of §54.1-3455 of the Drug Control Act.

### 18VAC110-20-622. Excluded veterinary anabolic steroid implant products.

The list of excluded veterinary anabolic steroid implant products ~~set forth in~~ pursuant to 21 CFR 1308.26 and maintained by the administrator of DEA is adopted only for legitimate veterinary use pursuant to the authority set forth in §§54.1-3443, 54.1-3450 and 54.1-3452 of the Drug Control Act; the exempted anabolic steroid products are drugs which are subject to the provisions of §54.1-3455 of the Drug Control Act when used for implant to cattle or other nonhuman species. These products

are not excluded from Schedule III if prescribed, administered, dispensed, or otherwise distributed for human use.

Part XVI

Medical Equipment Suppliers

**18VAC110-20-680. Medical equipment suppliers.**

A. A medical equipment supplier's location shall be inspected by the board prior to engaging in business. The location shall be clean and sanitary and shall have a system of temperature control to provide for specified storage conditions for any Schedule VI drug or device.

B. Hypodermic needles and syringes and Schedule VI drugs shall not be placed on open display or in an open area where patrons will have access to such items. No Schedule VI devices shall be placed in an area where responsible parties cannot exercise reasonable supervision and control.

C. A medical equipment supplier shall receive a valid order from a practitioner prior to dispensing and shall maintain this order on file on the premises for a period of two years from date of last dispensing. The original order may be kept at a centralized office as long as it is readily retrievable within 48 hours and a copy of the order is kept on the premises of the dispensing supplier. In lieu of a hard copy, an electronic image of an order may be maintained in an electronic database provided it preserves and provides an exact image of the order which is clearly legible and made available within 48 hours of a request by a person authorized by law to have access to prescription information.

D. Medical equipment suppliers shall make a record at the time of dispensing. This record shall be maintained on the premises for two years from date of dispensing and shall include:

1. Name and address of patient;

2. Item dispensed and quantity, if applicable; and

3. Date of dispensing.

Part XVII

Controlled Substances Registration for Other Persons or Entities

**18VAC110-20-690. Persons or entities authorized or required to obtain a controlled substances registration.**

A. A person or entity which maintains or intends to maintain a supply of Schedule II through Schedule VI controlled substances, other than manufacturers' samples, ~~in order to administer such drugs~~ in accordance with provisions of the Drug Control Act (§54.1-3400 et seq. of the Code of Virginia) may apply for a controlled substances registration on forms approved by the board.

B. Persons or entities which may be registered by the board shall include, but not be limited to, hospitals without in-house pharmacies, nursing homes without in-house pharmacies that use automated drug dispensing systems, ambulatory surgery centers, outpatient clinics, alternate delivery sites, and emergency medical services agencies provided such persons or entities are otherwise authorized by law and hold required licenses or appropriate credentials to administer the drugs for which the registration is being sought.

C. In determining whether to register an applicant, the board shall consider factors listed in subsections A and D of §54.1-3423 of the Code of Virginia and compliance with applicable requirements of this chapter.

1. The proposed location shall be inspected by an authorized agent of the board prior to issuance of a controlled substances registration.

2. Controlled substances registration applications which indicate a requested inspection date, or requests which are received after the application is filed, shall be honored provided a 14-day notice is allowed prior to the requested inspection date.

3. Requested inspection dates which do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.

4. Any person wishing to change an approved location of the drug stock or make structural changes to an existing approved drug storage location, or make changes to a previously approved

security system shall file an application with the board and be inspected consistent with subsection B.

5. Drugs shall not be stocked within the proposed drug storage location or moved to a new location until approval is granted by the board.

D. The application shall be signed by a person who will act as a responsible party for the controlled substances. The responsible party may be a prescriber; nurse; pharmacist; or pharmacy technician for alternate delivery sites; or other person approved by the board who is authorized to administer or otherwise possess the controlled substances for that type entity.

E. The board may require a person or entity to obtain a controlled substances registration upon a determination that Schedule II through VI controlled substances have been obtained and are being used as common stock by multiple practitioners and that one or more of the following factors exist:

1. A federal, state, or local government agency has reported that the person or entity has made large purchases of controlled substances in comparison with other persons or entities in the same classification or category.

2. The person or entity has experienced a diversion, theft, or other unusual loss of controlled substances which requires reporting pursuant to §54.1-3404 of the Drug Control Act.

3. The person or entity has failed to comply with recordkeeping requirements for controlled substances.

4. The person or entity or any other person with access to the common stock has violated any provision of federal, state, or local law or regulation relating to controlled substances.

**18VAC110-20-700. Requirements for supervision for controlled substances registrants.**

A. A practitioner licensed in Virginia shall provide supervision for all aspects of practice related to the maintenance and use of controlled substances as follows:

1. In a hospital or nursing home without an in-house pharmacy, a pharmacist shall supervise.

2. In an emergency medical services agency, the operational medical director shall supervise.

3. For any other ~~person or entity approved by the board, a practitioner of pharmacy, medicine, osteopathy, podiatry, dentistry, or veterinary medicine~~ type applicant or registrant, a pharmacist or a prescriber whose scope of practice is consistent with the practice of the ~~person or entity~~ applicant or registrant and who is approved by the board ~~shall~~ may provide the required supervision.

B. The supervising practitioner shall approve the list of drugs which may be ordered by the holder of the controlled substances registration; possession of controlled substances by the entity shall be limited to such approved drugs. The list of drugs approved by the supervising practitioner shall be maintained at the address listed on the controlled substances registration.

C. Access to the controlled substances shall be limited to the supervising practitioner or to those persons who are authorized by the supervising practitioner and who are authorized by law to administer drugs in Virginia, or to other such persons as designated by the supervising practitioner or the responsible party to have access in an emergency situation. If approved by the supervising practitioner, pharmacy technicians may have access for the purpose of delivering controlled substances to the registrant; stocking controlled substances in automated dispensing devices; conducting inventories, audits and other recordkeeping requirements; and overseeing delivery of dispensed prescriptions at an alternate delivery site.

D. The supervising practitioner shall establish procedures for and provide training as necessary to ensure compliance with all requirements of law and regulation, including, but not limited to, storage, security, and recordkeeping.

E. Within 14 days of a change in the responsible party or supervising practitioner assigned to the registration, either the responsible party or outgoing responsible party shall inform the Board and a new application shall be submitted indicating the name and license number, if applicable, of the new responsible party or supervising practitioner.

**18VAC110-20-710. Requirements for storage and security for controlled substances registrants.**

A. Drugs shall be stored under conditions which meet USP-NF specifications or manufacturers' suggested storage for each drug.

B. Any drug which has exceeded the expiration date shall not be administered; it shall be separated from the stock used for administration and maintained in a separate, locked area until properly disposed.

C. If a controlled substances registrant wishes to dispose of unwanted or expired Schedule II through VI drugs, he shall transfer the drugs to another person or entity authorized to possess and to provide for proper disposal of such drugs.

D. Drugs shall be maintained in a lockable cabinet, cart, device or other area which shall be locked at all times when not in use. The keys or access code shall be restricted to the supervising practitioner and persons designated access in accordance with 18VAC110-20-700 C.

E. In a facility not staffed 24 hours a day, the drugs shall be stored in a fixed and secured room, cabinet or area which has a security device for the detection of breaking which meets the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.

2. The installation ~~shall be hard wired and both the installation~~ and device shall be based on accepted ~~burglar~~ alarm industry standards.

3. The device shall be maintained in operating order, ~~and shall~~ have an auxiliary source of power, be monitored in accordance with accepted industry standards, be maintained in operating order; and shall be capable of sending an alarm signal to the monitoring entity if breached and the communication line is not operational.

4. The device shall fully protect all areas where prescription drugs are stored and shall be capable of detecting breaking by any means when activated.

5. Access to the alarm system shall be restricted to only designated and necessary persons, and the system shall be activated whenever the drug storage areas are closed for business.

6. An alarm system is not required for researchers, animal control officers, humane societies, or alternate delivery sites as provided in 18VAC110-20-275.

**VSHP may pursue the following legislative proposal for the 2009 session for the purpose of allowing certain multidose items to be stored in an automated dispensing device, such as insulin:**

**§ 54.1-3434.02. Automated drug dispensing systems.**

A. Hospitals licensed pursuant to Title 32.1 or Title 37.2 may use automated drug dispensing systems, as defined in § 54.1-3401, upon meeting the following conditions:

1. Drugs are placed in the automated drug dispensing system in a hospital and are under the control of a pharmacy providing services to the hospital;

2. The pharmacist-in-charge of the pharmacy providing services to the hospital has established procedures for assuring the accurate stocking and proper storage of drugs in the automated drug dispensing system and for ensuring accountability for and security of all drugs utilized in the automated drug dispensing system until the time such drugs are removed from the automated drug dispensing system for administration to the patients;

3. Removal of drugs from any automated drug dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber;

4. Adequate security for automated drug dispensing systems is provided, as evidenced by written policies and procedures, for (i) preventing unauthorized access, (ii) complying with federal and state regulations on prescribing and dispensing controlled substances, (iii) maintaining patient confidentiality, and (iv) assuring compliance with the requirements of this section;

5. Accountability for drugs dispensed from automated drug dispensing systems is vested in the pharmacist-in-charge of a pharmacy located within the hospital or the pharmacist-in-charge of any outside pharmacy providing pharmacy services to the hospital;

6. Filling and stocking of all drugs in automated drug dispensing systems shall be performed under the direction of the pharmacist-in-charge. The task of filling and stocking of drugs into an automated drug dispensing system shall be performed by a pharmacist or a registered pharmacy technician, who shall be an employee of the provider pharmacy and shall be properly trained in accordance with established standards set forth in a policy and procedure manual maintained by the provider pharmacy. The pharmacist stocking and filling the automated drug dispensing system or the pharmacist-in-charge, if the automated drug dispensing system is stocked and filled by a registered pharmacy technician, shall be responsible for the proper and accurate stocking and filling of the automated drug dispensing system.

B. Drugs placed into and removed from automated drug dispensing systems for administration to patients shall be in the manufacturer's or distributor's sealed original packaging or in unit-dose containers packaged by the pharmacy. *Drugs in multi-dose packaging, other than those administered orally, may be placed in such a device if approved by the pharmacist-in-charge in consultation with a standing hospital committee comprised of pharmacy, medical, and nursing staff.*

C. The pharmacist-in-charge in a pharmacy located within a hospital or the pharmacist-in-charge of any outside pharmacy providing pharmacy services to a hospital shall be responsible for establishing procedures for (i) periodically inspecting and auditing automated drug dispensing systems to assure the proper storage, security, and accountability for all drugs placed in and removed from automated drug dispensing systems, and (ii) reviewing the operation and maintenance of automated drug dispensing systems. This monitoring shall be reviewed by a pharmacist while on the premises of the hospital and in accordance with the pharmacist-in-charge's procedures and the Board of Pharmacy's regulations.

D. The Board of Pharmacy shall promulgate regulations establishing minimum requirements for random periodic inspections and monthly audits of automated drug dispensing systems to assure the proper storage, security, and accountability of all drugs placed in and removed from automated drug dispensing systems and for reviewing the operation and maintenance of automated drug dispensing systems.

**Project 1311 - Proposed**

**BOARD OF PHARMACY**

**Changes in renewal dates for pharmacies and permitted facilities**

**18VAC110-20-20. Fees.**

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Unless otherwise provided, any fees for taking required examinations shall be paid directly to the examination service as specified by the board.

C. Initial application fees.

| | |
|---|---|
| 1. Pharmacist license | $180 |
| 2. Pharmacy intern registration | $15 |
| 3. Pharmacy technician registration | $25 |
| 4. Pharmacy permit | $270 |
| 5. Permitted physician licensed to dispense drugs | $270 |
| 6. Medical equipment supplier permit | $180 |
| 7. Humane society permit | $20 |
| 8. Nonresident pharmacy | $270 |
| 9. Controlled substances registrations ~~(Between November 2, 2005, and December 31, 2006, the application fee for a controlled substance registration shall be $50)~~ | $90 |
| 10. Robotic pharmacy system approval | $150 |
| 11. Innovative program approval. If the board determines that a technical consultant is required in order to make a decision on approval, any consultant fee, not to exceed the actual cost, shall also be paid by the applicant in addition to the application fee. | $250 |
| 12. Approval of a pharmacy technician training program | $150 |
| 13. Approval of a continuing education program | $100 |

D. Annual renewal fees.

| | |
|---|---|
| 1. Pharmacist active license – due December 31 | $90 |
| 2. Pharmacist inactive license – due December 31 | $45 |
| 3. Pharmacy technician registration – due December 31 | $25 |
| 4. Pharmacy permit – due April 30 | $270 |
| 5. Physician permit to practice pharmacy – due February 28 | $270 |
| 6. Medical equipment supplier permit – due February 28 | $180 |
| 7. Humane society permit – due February 28 | $20 |
| 8. Nonresident pharmacy – due April 30 | $270 |

| | |
|---|---|
| 9. Controlled substances registrations – due February 28 | $90 |
| 10. Innovative program continued approval based on board order not to exceed $200 per approval period. | |

E. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date. In addition, engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.

| | |
|---|---|
| 1. Pharmacist license | $30 |
| 2. Pharmacist inactive license | $15 |
| 3. Pharmacy technician registration | $10 |
| 4. Pharmacy permit | $90 |
| 5. Physician permit to practice pharmacy | $90 |
| 6. Medical equipment supplier permit | $60 |
| 7. Humane society permit | $5 |
| 8. Nonresident pharmacy | $90 |
| 9. Controlled substances registrations | $30 |

F. Reinstatement fees. Any person or entity attempting to renew a license, permit, or registration more than one year after the expiration date shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following license revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

| | |
|---|---|
| 1. Pharmacist license | $210 |
| 2. Pharmacist license after revocation or suspension | $500 |
| 3. Pharmacy technician registration | $35 |
| 4. Pharmacy technician registration after revocation or suspension | $125 |
| 5. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees: | |
| a. Pharmacy permit | $240 |
| b. Physician permit to practice pharmacy | $240 |
| c. Medical equipment supplier permit | $210 |
| d. Humane society permit | $30 |
| e. Nonresident pharmacy | $115 |
| f. Controlled substances registration | $180 |

G. Application for change or inspection fees for facilities or other entities.

| | |
|---|---|
| 1. Change of pharmacist-in-charge | $50 |
| 2. Change of ownership for any facility | $50 |
| 3. Inspection for remodeling or change of location for any facility | 150 |
| 4. Reinspection of any facility | $150 |
| 5. Board-required inspection for a robotic pharmacy system | $150 |
| 6. Board-required inspection of an innovative program location | $150 |
| 7. Change of pharmacist responsible for an approved innovative program | $25 |

H. Miscellaneous fees.

| | |
|---|---|
| 1. Duplicate wall certificate | $25 |
| 2. Returned check | $35 |

~~I. For the annual renewal due on or before December 31, 2006, the following fees shall be imposed for a license, permit or registration:~~

| | |
|---|---|
| ~~1. Pharmacist active license~~ | ~~$50~~ |
| ~~2. Pharmacist inactive license~~ | ~~$25~~ |
| ~~3. Pharmacy technician registration~~ | ~~$15~~ |
| ~~4. Pharmacy permit~~ | ~~$210~~ |
| ~~5. Physician permit to practice pharmacy~~ | ~~$210~~ |
| ~~6. Medical equipment supplier permit~~ | ~~$140~~ |
| ~~7. Humane society permit~~ | ~~$20~~ |
| ~~8. Nonresident pharmacy~~ | ~~$210~~ |
| ~~9. Controlled substances registrations~~ | ~~$50~~ |

**18VAC110-50-20. Fees.**

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Initial application fees.

| | |
|---|---|
| 1. Nonrestricted manufacturer permit | $270 |
| 2. Restricted manufacturer permit | $180 |
| 3. Wholesale distributor license | $270 |
| 4. Warehouser permit | $270 |
| 5. Nonresident wholesale distributor | $270 |
| 6. Controlled substances registration | $90 |

C. Annual renewal fees shall be due on February 28 of each year.

| | |
|---|---|
| 1. Nonrestricted manufacturer permit | $270 |
| 2. Restricted manufacturer permit | $180 |

| | |
|---|---|
| 3. Wholesale distributor license | $270 |
| 4. Warehouser permit | $270 |
| 5. Nonresident wholesale distributor | $270 |
| 6. Controlled substances registration | $90 |

D. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date. In addition, engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.

| | |
|---|---|
| 1. Nonrestricted manufacturer permit | $90 |
| 2. Restricted manufacturer permit | $60 |
| 3. Wholesale distributor license | $90 |
| 4. Warehouser permit | $90 |
| 5. Nonresident wholesale distributor | $90 |
| 6. Controlled substances registration | $30 |

E. Reinstatement fees.

1. Any entity attempting to renew a license, permit, or registration more than one year after the expiration date shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following license revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

2. Engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement, but shall apply for a new permit or registration.

3. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:

| | |
|---|---|
| a. Nonrestricted manufacturer permit | $240 |
| b. Restricted manufacturer permit | $210 |
| c. Wholesale distributor license | $240 |
| d. Warehouser permit | $240 |
| e. Nonresident wholesale distributor | $240 |
| f. Controlled substances registration | $180 |

F. Application for change or inspection fees.

| | |
|---|---|
| 1. Reinspection fee | $150 |
| 2. Inspection fee for change of location, structural changes, or security system changes | $150 |

| | |
|---|---|
| 3. Change of ownership fee | $50 |
| 4. Change of responsible party | $50 |

G. The fee for a returned check shall be $35.

~~H. For the annual renewal due on or before December 31, 2006, the following fees shall be imposed for a license or permit:~~

| | |
|---|---|
| ~~1. Nonrestricted manufacturer permit~~ | ~~$210~~ |
| ~~2. Restricted manufacturer permit~~ | ~~$140~~ |
| ~~3. Wholesale distributor license~~ | ~~$210~~ |
| ~~4. Warehouser permit~~ | ~~$210~~ |
| ~~5. Nonresident wholesale distributor~~ | ~~$210~~ |

**Project 1341 - Proposed**

## BOARD OF PHARMACY

**18VAC110-20-25. Unprofessional conduct.**

The following practices shall constitute unprofessional conduct within the meaning of § 54.1-3316 of the Code of Virginia:

1. Failing to comply with provisions of § 32.1-127.1:03 of the Code of Virginia related to the confidentiality and disclosure of patient records or related to provision of patient records to another practitioner or to the patient or his personal representative;

2. Willfully or negligently breaching the confidentiality of a patient, unless otherwise required or permitted by applicable law;

3. Failing to maintain confidentiality of information received from the Prescription Monitoring Program, obtaining such information for reasons other than to assist in determining the validity of a prescription to be filled, or misusing information received from the program;

4. Engaging in disruptive or abusive behavior in a pharmacy or other health care setting that interferes with patient care or could reasonably be expected to adversely impact the quality of care rendered to a patient;

5. Engaging or attempting to engage in a relationship with a patient that constitutes a professional boundary violation in which the practitioner uses his professional position to take advantage of the vulnerability of a patient or his family, including but not limited to sexual misconduct with a patient, or other conduct that results or could result in personal gain at the expense of the patient;

6. Failing to maintain adequate safeguards against diversion of controlled substances;

7. Failing to appropriately respond to a known dispensing error in a manner that protects the health and safety of the patient;

8. Delegating a task within the practice of pharmacy to a person who is not adequately trained to perform such a task;

9. Failing by the PIC to ensure that pharmacy interns and pharmacy technicians working in the pharmacy are registered, and that such registration is current;

10. Failing to exercise professional judgment in determining whether a prescription meets requirements of law before dispensing.

**§ 54.1-3316. Refusal; revocation; suspension and denial.**

The Board may refuse to admit an applicant to any examination; refuse to issue a license, permit, certificate, or registration to any applicant; or reprimand, impose a monetary penalty, place on probation, impose such terms as it may designate, suspend for a stated period of time or indefinitely, or revoke any license, permit, certificate, or registration if it finds that an applicant or a person holding a license, permit, certificate, or registration:

1. Has been negligent in the practice of pharmacy or in any activity requiring a license, permit, certificate, or registration from the Board;

2. Has engaged in unprofessional conduct specified in regulations promulgated by the Board;

3. Has become incompetent to practice pharmacy or to engage in any activity requiring a license, permit, certificate, or registration from the Board because of a mental or physical condition;

4. Uses drugs or alcohol to the extent that he is rendered unsafe to practice pharmacy or to engage in any activity requiring a license, permit, certificate, or registration from the Board;

5. Has engaged in or attempted any fraud or deceit in connection with the practice of pharmacy or any activity requiring a license, permit, certificate, or registration from the Board, including any application to the Board for such license, permit, certificate, or registration;

6. Has engaged in activities beyond the scope of a license, permit, certificate, or registration or has assisted or allowed unlicensed persons to engage in the practice of pharmacy or perform duties related to the practice of pharmacy for which a license or registration is required;

7. Has violated or cooperated with others in violating any provisions of law or regulation relating to practice of pharmacy or any activity requiring a license, permit, certificate, or registration from the Board;

8. Has had revoked or suspended any registration issued by the United States Drug Enforcement Administration or other federal agency that is necessary to conduct an activity also requiring a license, permit, certificate, or registration from the Board;

9. Has engaged in the theft or diversion of controlled substances or has violated any federal drug law or any drug law of Virginia or of another state;

10. Has had denied, suspended, or revoked in any other state a license to practice pharmacy or any license, permit, certificate, or registration necessary to conduct an activity requiring a license, permit, certificate, or registration from the Board, or has surrendered in another state such license, permit, certificate, or registration;

11. Has been convicted of any felony or of any misdemeanor involving moral turpitude;

12. Has issued or published statements intended to deceive or defraud about his professional service or an activity requiring a license, permit, certificate, or registration from the Board;

13. Has conducted his practice, or activity requiring a license, permit, certificate, or registration from the Board in such a manner as to be a danger to the health and welfare of the public; or

14. Has failed to comply with requirements of this chapter or any regulation of the Board relating to continuing education.

**From:** Carey Potter [CPotter@NACDS.org]
**Sent:** Tuesday, November 04, 2008 4:55 PM
**To:** Russell, Scotti; Tim Musselman; Rebecca Snead; Kemper; Ayotte, Michael J.; Michelle Cope; Teresa; Sisto, John (Medco)
**Cc:** Yeatts, Elaine J.
**Subject:** RE: Regulation Committee Meeting November 13
Scotti,
NACDS has reviewed and we don□t find any concerns.
Thanks for asking.
Carey

---

**From:** Russell, Scotti [mailto:Scotti.Russell@DHP.VIRGINIA.GOV]
**Sent:** Tuesday, November 04, 2008 12:36 PM
**To:** Tim Musselman; Rebecca Snead; Kemper; Ayotte, Michael J.; Carey Potter; Michelle Cope; Teresa; Sisto, John (Medco)
**Cc:** Yeatts, Elaine J.
**Subject:** Regulation Committee Meeting November 13

Hello everyone,

There was a legislative change in 2007, that rewrote the Board's grounds for disciplinary sections-§§54.1-3315 and 3316. Prior to this change, unprofessional conduct was defined very narrowly include only #11 and 12 in the lanugage of new 3316 (below). The new language (#2) gives the Board the authority to define unprofessional conduct in regulation. The Board published a NOIRA in June 2008 stating that it intended to do this, but no comment was received during that NOIRA comment period. There was some discussion of this at the June Board meeting, and staff was asked to provide a draft at the September meeting for the Board to consider. The draft was to be based on such regulations of other Boards within this department as well as other boards of pharmacy. Staff also used examples of conduct reported as complaints to the department, which seemed to represent unprofessional conduct, but for which the Board had no authority to take disciplinary action. Some examples include sexual misconduct with a patient, physical assault of a patient/customer in a pharmacy, misuse of confidential information obtained within the practice of pharmacy, not appropriately responding to known dispensing errors.

The Board at its September 3 meeting reviewed the draft prepared by staff. There seemed to be some confusion on the part of Board members, and concern about some of the language. There were concerns from Board members that the regulations were somewhat vague, and Board counsel advised that grounds for disciplinary action should be general in nature, and not very specific, or there will be many cases that will not exactly match the grounds, and the Board will not be able to take appropriate action.

**From:** Tim Musselman [tim@virginiapharmacists.org]
**Sent:** Monday, November 10, 2008 11:39 AM
**To:** Russell, Scotti
**Cc:** Yeatts, Elaine J.; David Ivey
**Subject:** RE: Regulation Committee Meeting November 13
Scotti,

The only clarification I have on the language is #7 (7. Failing to appropriately respond to a known dispensing error in a manner that protects the health and safety of the patient;)

I would assume that the dispensing error is known to the pharmacist who must then respond in an appropriate manner (e.g., calling the patient to notify them, or made aware by the patient and then take action). But my questions is should the language be clarified to further cover the pharmacist and say something along the lines of □dispensing error known by the licensee□ to protect a pharmacist from a patient that notices an error but reports the pharmacist without notifying them of the error as the dispensing error would be □known□ but not necessarily by the dispensing pharmacist?

- Tim

**Timothy S. Musselman, Pharm.D.**
Associate Executive Director
Virginia Pharmacists Association
2530 Professional Road
Richmond, VA 23235
Phone: 804-285-4145, ext 303
Fax: 804-285-4227
tim@virginiapharmacists.org
www.virginiapharmacists.org

---

**From:** Russell, Scotti [mailto:Scotti.Russell@DHP.VIRGINIA.GOV]
**Sent:** Tuesday, November 04, 2008 1:36 PM
**To:** Tim Musselman; Rebecca Snead; Kemper; Ayotte, Michael J.; Potter, Carey; Michelle Cope; Teresa; Sisto, John (Medco)
**Cc:** Yeatts, Elaine J.
**Subject:** Regulation Committee Meeting November 13

Hello everyone,

There was a legislative change in 2007, that rewrote the Board's grounds for disciplinary sections-§§54.1-3315 and 3316. Prior to this change, unprofessional conduct was defined very narrowly include only #11 and 12 in the lanugage of new 3316 (below). The new language (#2) gives the Board the authority to define unprofessional conduct in regulation. The Board published a NOIRA in June 2008 stating that it intended to do this, but no comment was received during that NOIRA comment period. There was some discussion of this at the June Board meeting, and staff was asked to provide a draft at the September meeting for the Board to consider. The draft was to be based on such regulations of other Boards within this department as well as other boards of

**From:** Teresa [Teresa@VantagePointConsulting.com]
**Sent:** Monday, November 10, 2008 10:38 AM
**To:** Russell, Scotti
**Subject:** RE: Regulation Committee Meeting November 13

Hey Scotti--VSHP is fine with this--T

Teresa T. Gregson
Vantage Point Consulting, LLC
P.O. Box 17423
Richmond, VA 23226
P 804.225.8464
F 804.225.8465

-------- Original Message --------
Subject: Regulation Committee Meeting November 13
From: "Russell, Scotti" <Scotti.Russell@DHP.VIRGINIA.GOV>
Date: Tue, November 04, 2008 1:35 pm
To: "Tim Musselman" <Tim@vapharmacy.org>, "Rebecca Snead" <Becky@naspa.us>, "Kemper" <kempco@comcast.net>, "Ayotte, Michael J." <mjayotte@cvs.com>, "Potter, Carey" <cpotter@nacds.org>, "Michelle Cope" <mcope@NACDS.org>, "Teresa" <Teresa@VantagePointConsulting.com>, "Sisto, John (Medco)" <john_sisto@medco.com>
Cc: "Yeatts, Elaine J." <Elaine.Yeatts@DHP.VIRGINIA.GOV>

Hello everyone,

There was a legislative change in 2007, that rewrote the Board's grounds for disciplinary sections-§§54.1-3315 and 3316. Prior to this change, unprofessional conduct was defined very narrowly include only #11 and 12 in the lanugage of new 3316 (below). The new language (#2) gives the Board the authority to define unprofessional conduct in regulation. The Board published a NOIRA in June 2008 stating that it intended to do this, but no comment was received during that NOIRA comment period. There was some discussion of this at the June Board meeting, and staff was asked to provide a draft at the September meeting for the Board to consider. The draft was to be based on such regulations of other Boards

**Issue:**

With the new statutory requirement staff has been asked about interpretation of the new law. The law requires non-resident pharmacies who are not PBMs to designate a Virginia-licensed pharmacist to serve as PIC on the non-resident registration for the purpose of ensuring compliance with applicable Virginia laws.

In Virginia pharmacies the PIC must be fully engaged in the practice of pharmacy at the pharmacy location. Additionally, in Virginia a pharmacist may only be PIC of a maximum of two pharmacies.

The Board has received a number of requests to allow a pharmacist to be "PIC" of multiple pharmacies. One case involves five outpatient pharmacies of a major hospital system that want to provide continued pharmacy services to patients being treated by the hospital system, and want the one pharmacy regional manager for all the pharmacies to be the PIC. Most other requests for multiple PIC locations comes from pharmacies who want to ccontract with a "consultant" pharmacist who is licensed in Virginia, and for example may be living in Florida with the non-resident pharmacy in Wisconsin. They may or may not be traveling to the pharmacy periodically to actually work at the location. They may or may not be reviewing Virginia orders electronically. There are businesses that are advertising these type of pharmacist services. We have also received a couple of requests from pharmacies who have a very limited scope of business in Virginia, and want the Board to be able to waive this requirement under a limited-use registration. One example is an entity licensed as a pharmacy in one state, but are only dispensing one prescription device to Virginia residents, no drugs. Another entity wants to be able to provide pharmacy services to his own patrons who may be visiting in Virginia for an extended vacation/partial residence, and to date has only dispensed three prescriptions.

The questions are as follows:

1. **Can we exceed the no more than PIC of two pharmacies for non-resident pharmacies?**
2. **Does the designated PIC for a non-resident pharmacy have to be engaged in practice at the location of the pharmacy?**
3. **Is the Board able to designate a non-resident pharmacy a limited-use, and as such waive the requirements for the Virginia licensed PIC, or if no, for the PIC to be practicing at the pharmacy location.**

**§ 54.1-3434.1. Nonresident pharmacies to register with Board.**

A. Any pharmacy located outside the Commonwealth that ships, mails, or delivers, in any manner, Schedule II through VI drugs or devices pursuant to a prescription into the Commonwealth shall be considered a nonresident pharmacy, shall be registered with the Board, shall designate a pharmacist in charge who is licensed as a pharmacist in Virginia and is responsible for the pharmacy's compliance with this chapter, and shall disclose to the Board all of the following:

1. The location, names, and titles of all principal corporate officers and the name and Virginia license number of the designated pharmacist in charge, if applicable. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, or pharmacist in charge.

2. That it maintains, at all times, a current unrestricted license, permit, certificate, or registration to conduct the pharmacy in compliance with the laws of the jurisdiction, within the United States or within another jurisdiction that may lawfully deliver prescription drugs directly or indirectly to consumers within the United States, in which it is a resident. The pharmacy shall also certify that it complies with all lawful directions and requests for information from the regulatory or licensing agency of the jurisdiction in which it is licensed as well as with all requests for information made by the Board pursuant to this section.

3. As a prerequisite to registering with the Board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located. The inspection report shall be deemed current if the inspection was conducted within the past five years. However, if the nonresident pharmacy has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed within the past five years, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

4. For a nonresident pharmacy that dispenses more than 50 percent of its total prescription volume pursuant to an original prescription order received as a result of solicitation on the Internet, including the solicitation by electronic mail, that it is credentialed and has been inspected and that it has received certification from the National Association of Boards of Pharmacy that it is a Verified Internet Pharmacy Practice Site, or has received certification from a substantially similar program approved by the Board. The Board may, in its discretion, waive the requirements of this subdivision for a nonresident pharmacy that only does business within the Commonwealth in limited transactions.

5. That it maintains its records of prescription drugs or dangerous drugs or devices dispensed to patients in the Commonwealth so that the records are readily retrievable from the records of other drugs dispensed and provides a copy or report of such dispensing records to the Board, its authorized agents, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of a request.

6. That its pharmacists do not knowingly fill or dispense a prescription for a patient in Virginia in violation of § 54.1-3303 and that it has informed its pharmacists that a pharmacist who dispenses a prescription that he knows or should have known was not written pursuant to a bona fide practitioner-patient relationship is guilty of unlawful distribution of a controlled substance in violation of § 18.2-248.

The requirement that a nonresident pharmacy have a Virginia licensed pharmacist in charge shall not apply to a registered nonresident pharmacy that provides services as a pharmacy benefits administrator.

B. Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in the Commonwealth and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in the Commonwealth.

C. Pharmacies subject to this section shall comply with the reporting requirements of the Prescription Monitoring Program as set forth in § 54.1-2521.

D. The registration fee shall be the fee specified for pharmacies within Virginia.

E. A nonresident pharmacy shall only deliver controlled substances that are dispensed pursuant to a prescription, directly to the consumer or his designated agent, or directly to a pharmacy located in Virginia pursuant to regulations of the Board.

**§ 54.1-3434. Permit to conduct pharmacy.**

No person shall conduct a pharmacy without first obtaining a permit from the Board.

The application for such permit shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the pharmacy and who will be fully engaged in the practice of pharmacy at the location designated on the application.

...

**18VAC110-20-110. Pharmacy permits generally.**

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies.

...

**18VAC110-20-120. Special or limited-use pharmacy permits.**

For good cause shown, the board may issue a special or limited-use pharmacy permit, when the scope, degree or type of pharmacy practice or service to be provided is of a special, limited or unusual nature as compared to a regular pharmacy service. The permit to be issued shall be based on special conditions of use requested by the applicant and imposed by the board in cases where certain requirements of regulations may be waived. The following conditions shall apply:

1. The application shall list the regulatory requirements for which a waiver is requested and a brief explanation as to why each requirement should not apply to that practice.

2. A policy and procedure manual detailing the type and method of operation, hours of operation, schedules of drugs to be maintained by the pharmacy, and method of documentation of continuing pharmacist control must accompany the application.

3. The issuance and continuation of such permits shall be subject to continuing compliance with the conditions set forth by the board.

**Institute for the Certification of Pharmacy Technicians**
2536 S Old Hwy 94, Suite 214, St. Charles, MO 63303
www.nationaltechexam.org
Phone: 314-442-6775
Fax: 866- 203-9213

October 3, 2008

Scotti Russell
Executive Director
Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond Virginia 23233-1463

Dear Scotti,

I am writing to request approval of the Exam for the Certification of Pharmacy Technicians (ExCPT) under 18VAC110-20-101 Application for registration as a pharmacy technician in Virginia. With the approval of the ExCPT we would also request inclusion of the ExCPT in 18VAC110-20-102.C where instructors are discussed and 18VAC110-20-105.D where reinstatement is discussed. In June 2008, ICPT received accreditation of the ExCPT from the National Commission for Certifying Agencies (NCCA).

18VAC110-20-103A states "The Board shall approve one or more examinations to test entry-level competency for pharmacy technicians." Having more than one exam available is very common in many professions and industries (See attachment 1 for a partial list). Even APhA, ASHP and NABP have recognized at one point that State Boards may approve more than one certification exam (See attachment 2). We welcome competition and recognize that competition benefits pharmacies, pharmacy technicians and pharmacy boards by forcing both new programs and former monopolies to improve their services, refrain from increasing costs and to become more responsive to stakeholders. Competition will benefit the pharmacy profession.

We recognize that 18VAC110-20-103 also speaks to the need for the exam to 'meet the recognized acceptable test measurement standards of the Joint Technical Standards for Education and Psychological Testing (American Psychological Association, current edition)'. ICPT appreciates the importance of the American Psychological Association standards to the Virginia Board of Pharmacy. We respectfully refer to the Virginia Board of Pharmacy Minutes for March 29, 2007 where it was acknowledged that NCCA accreditation incorporates APA standards (as required by Virginia statute). It was also noted in those minutes that the Board unanimously voted that it would consider approval of a second exam but would only consider ExCPT upon documentation of psychometric

soundness and meeting the APA standards. A reference from the National Organization for Competency Assurance website speaks specifically to the APA standards:

> The National Commission for Certifying Agencies (NCCA or the Commission) is the accreditation body of NOCA. The Commission reviews and accredits certification programs that demonstrate compliance with each accreditation standard. NCCA's *Standards* exceed the requirements set forth by the American Psychological Association and the U.S. Equal Employment Opportunity Commission.

(http://www.noca.org/MembersOnly/CommitteeDirectory/NCCACommissioners/tabid/127/Default.aspx)

With the NCCA accreditation of the ExCPT, we feel there are three key reasons to approve the ExCPT in Virginia.

***Accreditation***
First, the ExCPT is accredited by the National Commission for Certifying Agencies (NCCA). NCCA, the accrediting arm of the National Commission for Competency Assurance, sets aggressive certification industry standards, which exceed those of the American Psychological Association. The Virginia Board of Pharmacy should feel confident that this accreditation demonstrates the ExCPT meets the criteria outlined by the National Association of Boards of Pharmacy for the psychometric evaluation of technician certification exams.

***Registration on-demand***
Secondly, the exam is offered conveniently on-demand with 12 locations in Virginia, versus three for PTCB, and over 300 testing days a year. There are no testing windows requiring technicians to wait for a testing opportunity. A list of test sites in Virginia is shown in Attachment 3.

***Immediate Feedback***
Technicians know upon completion of the exam whether they have achieved a passing score. Technicians who do achieve a passing score will receive a formal certificate within 10 days; a diagnostic report that outlines performance against the ExCPT blueprint is provided to all technicians who do not achieve a passing score. ICPT will make available to the Virginia Board of Pharmacy a login to the database of certified pharmacy technicians at no cost.

To further assist the Board in their review, I have enclosed a copy of the ExCPT Candidate's Guide that contains the exam blueprint in addition to policies and procedures for certification and recertification.

At one time there was only one choice for a national pharmacy technician certification program, however, that is no longer the case. We believe that it is beneficial to allow competition in this arena as it improves services offered to all constituencies. As you may be aware, many State Boards of Pharmacy have reviewed and do recognize the ExCPT exam offered through ICPT. I have included the ExCPT status for each state in an enclosure.

If there are other questions or concerns, please contact me at any time. ICPT would like to attend the meeting on December 10th to discuss this request and hopefully obtain

Board approval. Please advise us of the meeting details so we can make arrangements to attend. We are certainly available at any time to answer questions or provide additional information the Board may need.

Sincerely,

Rebecca M. Rabbitt, MS, PharmD
Chief Executive Officer, ICPT
Sponsors of ExCPT

Encl: Candidate's Guide
NCCA Accreditation letter

**Attachment 1**

**Partial List of Professions and Industries that Have Competing Certification/Accreditation/Assessment Programs**

- Computer industry
- Cosmeticians
- Electricians
- Financial planners
- Insurance industry
- Medical equipment supplies
- Nursing

Other Examples of Competing Accreditation/Certification Programs and Assessment Exams:

- Competing Accreditation Programs for Managed Care Organizations
  - National Commission on Quality Assessment (NCQA)
  - Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
  - Utilization Review Accreditation Council (URAC)

- Competing Certification Programs for Managed Care Professionals
  - Professional, Academy for Healthcare Management (PAHM)
  - Fellow, Academy for Healthcare Management (FAHM)
  - Managed Healthcare Professional (MHP)
  - Certified Employee Benefit Specialist (CEBS)
  - Certified Managed Care Pharmacist (CMCP)

- College Admissions Exams
  - SAT versus ACT
  - GRE versus GMAT

- Providers of continuing education
  - ACPE- approved providers
  - State Board approval of CE programs

- According to the *ACPE White Paper on Pharmacy Technicians*, there are at last four organizations that accredit pharmacy technician training programs:
  - The Accrediting Commission of Career Schools and Colleges of Technology (ACCSCT)
  - The Accrediting Bureau of Health Education Schools (ABHES)
  - The Council on Occupational Education (COE)
  - The Accrediting Council for Independent Colleges and Schools (ACICS)

**Attachment 2**
**Statements Recognizing that State Boards of Pharmacy Will Approve Multiple Pharmacy Technician Certification Programs**

All three national financial partners of PTCB have recognized that state boards of pharmacy will recognize more than just one pharmacy technician certification program.

"In order to be registered as a Certified Pharmacy Technician in this state, an applicant shall:...(5) have successfully passed an examination **or examinations approved by the Board of Pharmacy**..."

*- Section 307(a), NABP Model State Pharmacy Practice Act*

"ASHP supports certification by PTCB **or another comparable nationally validated, psychometrically sound certification program approved by the state board of pharmacy**."

*- ASHP Policy 0412*

The Stepping Stone Summit Two report discussed 3 possible levels of education and training...level 2 would require that, "The individual should be qualified to sit for the PTCB certification **or other state board-recognized examination**."

*- Report of APhA's Stepping Stone Summit Two: Pharmacy Technicians, 2002*

## Attachment 3 – Virginia Testing Sites

| | | | |
|---|---|---|---|
| Manassas Aviation Center Inc. | 10601 Observation Road | Manassas | VA 20110 |
| PSI Testing-Falls Church | 6201 Leesburg Pike-Ste 404-McIlvaine Bldg | Falls Church | VA 22044 |
| PSI Testing-Tysons Corner | 1651 Old Meadow Rd - Ste B01 | Mclean | VA 22102 |
| AV ED Ground School | 8298A Old Courthouse Road | Vienna | VA 22182 |
| PSI Testing-Charlottesville | 2114 Angus Rd - Ste 105-B | Charlottesville | VA 22901 |
| PSI Testing-Richmond | 3805 Cutshaw Ave-Ste 310-Daniel Bldg | Richmond | VA 23230 |
| Horizon Flight Center | 1777 West Rd | Chesapeake | VA 23323 |
| PSI Testing-Norfolk-Virginia Beach | 291 Independence Blvd-Pembroke IV Bldg-Ste 140 | Virginia Beach | VA 23462 |
| PSI Testing-Roanoke | 2847 Penn Forest Blvd-Bldg D-Ste 200 | Roanoke | VA 24018 |
| LC's Flying Service dba New River Aero | 1607 Tech Center Drive | Blacksburg | VA 24060 |
| Mountain Empire Comm Coll | US Highway 23 S | Big Stone Gap | VA 24219 |
| Virginia Aviation | P O Box 4209 | Lynchburg | VA 24502 |

Applied Measurement Professionals, Inc.


October 16, 2008

Elizabeth Scott Russell
Executive Director
Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond Virginia 23233-1463

Dear Ms. Russel,

The Exam for the Certification of Pharmacy Technicians (ExCPT) recently received accreditation from the National Commission for Certification Agencies (NCCA). The psychometric standards promulgated by NCCA are consistent with the Standards for Education and Psychological Testing developed by the AERA/APA/NCME. The NCCA Standards stress that public protection is one of the primary goals for a licensure/certification examination program. The review process is conducted by three independent psychometricians to determine if all NCCA Standards are met, including subject matter expert item review, and the establishment of a criterion-referenced passing score.

Additionally, the NCCA standards add sound administrative requirements that the organization must meet. In that sense, the NCCA Standards can be considered to exceed the Joint Technical Standards. NCCA accreditation should ensure the Virginia BOP that the ExCPT meets all current psychometric and administrative standards.

Sincerely,

Steven S. Nettles, EdD
Senior Vice-President, Psychometrics

cc: Rebecca M. Rabbitt, MS, PharmD
Chief Executive Officer, ICPT
Sponsors of ExCPT

# The National Commission for Certifying Agencies

has recognized the

*Institute for the Certification of Pharmacy Technicians*
*Certified Pharmacy Technician*

as an accredited certification program
together with all rights and privileges thereto pertaining

*through May 31st, 2013*

Denise Fondal
Chair

Executive Director